

REMARKS

Claims 1-3, 5, 6, 9-14, 17, and 21-23 are pending. Claims 4, 7, 8, 15, 16, and 18-20 are canceled. By virtue of this response, claims 1 and 9 are amended. New claims 21-23 have been added. Therefore, claims 1-3, 5, 6, 9-14, 17, and 21-23 are under examination. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter is added.

I. Claim Rejections Under 35 USC §112, first paragraph, written description

Claims 1-3, 5-6, 9-14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

Applicant respectfully traverses the rejection and its supporting remarks. The claims have been amended to “80% or more identity” and “a fragment of at least 30 consecutive amino acids” from each referenced SEQ ID NO. The specification provides a wealth of data regarding each of the five antigens including references to additional data generated by the assignee.

Cripps *et al.* as cited by the Examiner is particularly relevant to this combination of five antigens. The assignee has been engaged in high-throughput genomic analysis to identify an ideal set of protein antigens from *N. meningitidis* as suggested by Cripps *et al.* (well before the publication of Cripps *et al.*). In the process of identifying this particular combination as the optimal combination of antigens, the assignee has developed a wealth of data on these five antigens as individual antigens and as combinations thereof (and combinations with other antigens that were ultimately rejected). This information is summarized in the specification starting on page 11, line 18 and extending through page 13, lines 32 of the specification. More importantly, this section of the specification includes references to other patent applications filed by the assignee that includes much of the data on these individual antigens and pairwise combinations thereof. By way of example, reference 85 discloses 741 variants from 22 different strains of *N. meningitidis* and includes a sequence alignment of these sequences as Figure 1. In addition, the specification discloses data on a number of pair-wise combinations of 741 from multiple different strains with other antigens such as the 287 antigen and the 936 antigen (as well as other combinations of the

claimed antigens – note: NadA was referred to as 961 in a number of these earlier patent applications). All of these constructs showed some degree of ability to induce a serum bactericidal response. Reference 82 discloses the 287 antigen from 35 strains (see Figure 15 for an alignment) and the 953 antigen from 8 strains (see Figure 19 for an alignment). Additional NadA sequences can be found in reference 98 (see Figure 9). The specification confirms that the combination of all five antigens provide strong cross-strain protection (*see, e.g.*, page 32, line 3 through page 33, line 13). Thus, one of skill in the art would understand that the Applicant had possession of the full scope of the currently pending claims.

Applicant therefore respectfully requests that the Examiner withdraw the rejection of claims 1-3, 5-6, 9-14 and 17.

II. Claim Rejections Under 35 USC §112, first paragraph, enablement

Claims 1-3, 5-6, 9-14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Applicant respectfully traverses the rejection and its supporting remarks. As discussed above, the claims have been amended to “80% or more identity” and “a fragment of at least 30 consecutive amino acids” from each referenced SEQ ID NO, and the specification provides a wealth of data regarding each of the five antigens including references to additional data generated by the assignee. Applicant therefore respectfully asserts that it would not require undue experimentation to make and use the claimed invention.

Applicant therefore respectfully requests that the Examiner withdraw the rejection of claims 1-3, 5-6, 9-14 and 17.

III. Claim Rejections Under 35 USC §102

Claims 1-3, 5-6, 9-13, and 17 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Costantino (US Publ. 2007/00820124).

Applicant respectfully traverses the rejection and its supporting remarks. Costantino is not available as 102(e) prior art with respect to the currently pending claims. The 102(e) date of a

U.S. Patent Publication does not include claims of priority to foreign patent applications. Therefore, Costantino is only entitled to a 102(e) date of January 30, 2004. The pending claims have an effective date of October 2, 2003 (*see, e.g.*, claim 8 on page 39 of the earliest priority application), which is before the 102(e) date of Costantino.

Applicant therefore respectfully requests that the Examiner withdraw the rejection of claims 1-3, 5-6, 9-13 and 17.

IV. Claim Rejections Under Obviousness-Type Double-Patenting

Claims 1-3, 9-14, and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26-63 of U.S. Ser. No. 10/543,455.

Applicant respectfully requests that the Examiner hold this rejection in abeyance until such time as there is an indication of otherwise allowable subject matter. Only at that time will the applicants be able to determine whether an obviousness-type double patenting rejection is applicable given that the claims in this or the referenced patent application may be further amended during prosecution and withdrawal of a terminal disclaimer is highly disfavored.

V. Objection to the Specification

The specification has been objected to for the incorporation by reference of the priority patent applications.

Applicant has amended the specification to remove the incorporation by reference.

Applicant therefore respectfully requests that the Examiner withdraw the objection to the specification.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 223002118100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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